DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
Rockville MD 20857

'02 AUG 19 P1:36

July 17, 2002

William B. Schultz
Zuckerman Spaeder LLP
1201 Connecticut Avenue, N.W.
Washington, D.C. 20036

Matthew Myers
William Corr
National Center for Tobacco-Free Kids, Inc.
1400 Eye Street, N.W., Suite 1200
Washington, D.C. 20005

Re: Docket Nos. 01P-0570, 01P-0571, 01P-0572

Dear Messrs. Schultz, Myers, and Corr:

I am writing to inform you that the Food and Drug Administration (FDA) is still considering the issues raised in the citizen petitions referenced above submitted by you December 18, 2001, on behalf of the National Center for Tobacco-Free Kids, Inc., the American Cancer Society, the American College of Preventive Medicine, and other health and medical organizations. These petitions request that FDA assert jurisdiction over a number of nicotine- and tobacco-containing products including Ariva, Eclipse, "OMNI", and Advance, and regulate them under provisions of the Food, Drug, and Cosmetic Act (the Act). As you know, the agency recently granted your related citizen petition, Docket No. 01P-0573, requesting that FDA regulate nicotine water as a drug within the meaning of the Act.

FDA has been unable to reach a decision on the remaining petitions because they raise significant and complex issues requiring extensive review and analysis by Agency officials. Because of their complexity, we are still considering the issues raised in the petitions. This interim response is provided in accordance with FDA regulations on citizen petitions. See 21 CFR 10.30(e)(2). We will respond to your petition as soon as we have reached a decision on your requests.

Sincerely,

Margaret Dotzel
Associate Commissioner for Policy

01P-0572

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